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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,462	08/14/2006	Yukiko Inamoto	2006_1261A	7229

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EXAMINER	
RAO, SAVITHA M	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
09/20/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/589,462	INAMOTO ET AL.	
	Examiner	Art Unit	
	SAVITHA RAO	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/11/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The office action mailed on 06/24/2010 is hereby withdrawn due to correction in the conclusion set forth in the instant office action.

Claims 4-7 are pending.

Receipt and consideration of Applicants' amended claim set and remarks/arguments filed on 03/24/2010 is acknowledged. Applicant amended instant claim 1 and cancelled claim 8

Applicants' arguments, filed 03/24/2010 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

(New matter rejection)

New grounds of Rejection:

> The following is a quotation of the first paragraph of 35 U.S.C. 112:
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 6-7 recites the limitation "**The 20% by weight concentration of acetylsalicylic acid or pharmaceutical salt of acetylsalicylic acid**". It is noted that the only 20% by weight disclosure as filed is in Example 13 in the specification and this is in a specific composition and not generic as to what is present with the 20% aspirin as is the scope of instant claims 6 and 7. In addition the all the examples in the specification uses just the acid form of acetylsalicylic acid which again is taught in a specific composition and is not generic to what is present with the acetylsalicylic acid and in addition the specification does not teach the pharmaceutical salts of acetylsalicylic acid as instantly claimed in a composition. Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that the Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975. Accordingly, claims 1-4, 7, 12-14 and 16-32 is properly rejected under 35 U.S.C. 112 for new matter addition in the claims.

Claim Rejections - 35 USC § 103

New grounds of rejection necessitated by Amendment dated 03/24/2010

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inamoto et al (US 2003/0125308 an English equivalent of WO2001/047525,) as evidenced by Reller (US 4219548) (both references already of record) further in view of Baxter (Nursing Times, Vol.99, No 13, 2003, pages 1-5).

Inamoto discloses external preparations having an excellent antipruritic activity acetylsalicylic acid as an active ingredients and a method of treating pruritis by using said external preparations [0001]. Inamoto discloses that acetylsalicylic acid (aspirin)

has a strong analgesic activity, antifebrile activity and an antirheumatic activity being less on its side effects and superior in its safety [0006]. Inamoto also discloses that a new use of acetylsalicylic acid in the form of an external preparation, ointments for treating neuralgia and external preparations for treating skin injury and a transdermal administration system for treatment of thrombosis and prophylactic treatment of cancer has been illustrated in prior art [0008].

Inamoto discloses that the amount of acetyl salicylic acid in the external preparation depends on form of the preparation and is in the range of 0.05-80%, preferably 0.05-70%, more preferably 0.1-50% per total amount by weight. Inamoto additionally discloses that if the aspirin amount is greater than 80% by weight, it is impossible to maintain the physical property of an external preparation and when it is less than 0.05% by weight, there is not enough antipruritic activity and therefore the amount of more than 80% or less than 0.05% is not preferable [0014]. Inamoto teaches examples of diseases with itching for which the external preparation of his invention is used as itching with skin diseases, such as atopic dermatitis, eczema, contact dermatitis etc.; senile pruritis; itching with metabolic diseases, such as hepatocirrhosis etc., itching with endocrine or dyshormonic disease such as diabetes; and itching with skin injury, such as cut, **wound after operation**, or burn [0015]. Inamoto further provides examples of external formulations comprising acetylsalicylic acid (examples 1-25, Tables 1-4, [0027-0030]). Inamoto finally teaches that the preparation as per his invention is applied to the lesion [0025].

Reller is being provided as a supplemental reference to demonstrate the routine knowledge in using acetylsalicylic acid as active ingredient in topical composition that is useful for the treatment of inflammation of skin including dermatoses accompanied by inflammation, skin injury, contact burns and insect bites (see column 1, lines 18-43; column 1, line 66 through column 2, line 3; Example I-II). Particularly, Example II teaches that topical administration of aspirin is useful in reducing inflammation and the sensation of itching and pain.

Inamoto fails to teach wherein the skin wound is a result of infectious disease in surgery or wound of the vessel and lymphangiopathy

However, Baxter teaches that one of the potential surgical complication is infection (page 4, 2nd paragraph) and **surgical wound infection** (infectious disease after surgery as instantly claimed) is characterized by redness**, pain,** heat and swelling of the wound and periwound and Baxter further teaches that persistence **inflammation** may indicate infection area (page 4, 5th paragraph).

With regards to instant claims 6-7, Inamoto's teachings that the external preparation of his invention comprises acetylsalicylic acid in the concentrations range of 0.05-80%, preferably 0.05-70%, more preferably 0.1-50% per total amount by weight, encompasses the instantly claimed ranges and thereby renders the instant claims obvious. Inamoto's additional teachings that having concentrations less than 0.05% or greater than 80% would not result in a stable composition provides an ordinarily skilled artisan additional motivation to further optimize the concentration to narrow down the dose range, thereby arriving at the instantly claimed concentrations. Additionally, It is

noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In view of the foregoing references it would have been prima facia obvious to develop a method of treating skin wound and alleviate pain by topical administration of aspirin (acetylsalicylic acid) to the infectious wounds resulting form surgery. Inamoto discloses that acetylsalicylic acid (aspirin) has a strong analgesic activity, use of acetylsalicylic acid in the form of an external preparation for treating neuralgia and external preparations for treating skin injury and further teaches the use of aspirin as a to treat itching associated with sin injury such as wound after operation. Baxter teaches that surgical wound infections are characterized by pain, heat and swelling and inflammation all of which can be treated by aspirin. Accordingly, it would have been obvious to an ordinarily skilled artisan to utilize topical aspirin at the sites of the infected post surgical wounds to reduce pain, decrease inflammation and itching and as such promote healing. A skilled artisan is motivated to do so from the prior art teachings of the pain killing, anti-inflammatory and anti-itch properties of topical aspirin. Further, absent factual evidence to the contrary. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).Office lacks laboratory facilities to test the prior art compounds and compositions. Accordingly, the aspirin taught by

Inamoto et al. has the property of reducing pain, inflammation and itch and would elicit these properties on any type of wounds when applied since wounds are typically accompanied by pain and inflammation as taught by Baxter.

Response to applicant's arguments submitted on 03/24/2010

Applicant's arguments with respect to the previous rejection of the claims over Inamoto and Reller or Mizubuchi and Reller have been considered but are moot and are not persuasive in light of these new ground of rejection necessitated by Applicant's amendments to the claims.

Conclusion

Claims 4-7 are rejected. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7 am to 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614